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Atty Dkt No. 021286-0306473  
Pat. App. Ser. No. 10/693,629

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re PATENT APPLICATION OF

Mikayama et al.

Group Art Unit: 1644

Appln. No.: 10/693,629

Examiner: to be assigned

Filed: October 23, 2003

Title: ANTI-CD40 MONOCLONAL ANTIBODY

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Attached is Form PTO-1449 listing the cited references in this statement.

All cited references except for U.S. patent documents are enclosed herewith.

Contingent Request Under Rule 97(c): Should a first action on the merits have been issued on the same day or before this Information Disclosure Statement is filed, please accept this Information Disclosure Statement under Rule 97(c) and charge the requisite Rule 17(p) fee to our Deposit Account No. 50-2212, under the above Atty Dkt. No., and proceed to consider this Information Disclosure Statement.

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By:

  
Sachiko Y. Snedden

Date: July 26, 2004

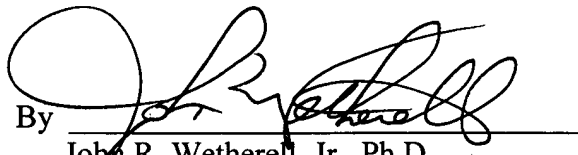
This IDS is intended to be in full compliance with the rules, but should the Examiner find any part of its required content to have been omitted, prompt notice to that effect is earnestly solicited, along with additional time under Rule 97(f), to enable Applicant to comply fully.

This Information Disclosure Statement is not to be constructed as a representation that any of the listed citations establishes, by itself or in combination with other information, a prima facie case of unpatentability of any claim in the above-identified patent application. Additionally, this Information Disclosure Statement is not to be constructed as a representation that a further search of the art has been made by the Applicant, or that additional information unknown to the Applicant and relevant to the examination of this patent application does not exist.

Consideration of the foregoing and enclosures plus the return of a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column per MPEP 609 are earnestly solicited along with an early action on the merits.

Respectfully submitted,

Pillsbury Winthrop LLP

By   
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**TRANSMITTAL LETTER**

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Date: July 26, 2004 By:

  
Sachiko Y. Snedden

Sir:

Transmitted herewith for filing are the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Cited References (60) except for U.S. patent documents (7); and
4. Return Postcard.

No fee is believed to be incurred for filing this Inquiry. However, the Commissioner is hereby authorized to charge any fee that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account 50-2212. A duplicate of this Transmittal is enclosed.

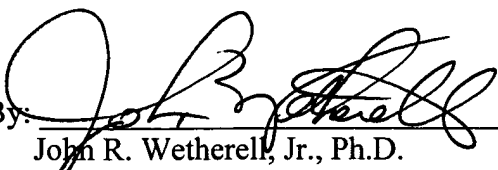
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## **U.S. PATENT DOCUMENTS**

Examiner's Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
	AR	5,677,165	10/1997	de Boer et al.			
	BR	5,786,456	07/1998	Ledbetter et al.			
	CR	5,801,227	09/1998	Fanslow, III et al.			
	DR	5,874,082	02/1999	de Boer			
	ER	6,004,552	12/1999	de Boer et al.			
	FR	6,051,228	04/2000	Aruffo et al.			
	GR	6,150,584	11/2000	Kucherlapati et al.			

## **FOREIGN PATENT DOCUMENTS**

Examiner's Initials*		Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract		Translation Readily Available	
						Enclosed	No	Enclosed	No
	HR	91/09115	06/1991	WIPO	Banchereau et al.				
	IR	96/33735	10/1996	WIPO	Kucherlapati et al.				
	JR	96/34096	10/1996	WIPO	Kucherlapati et al.				
	KR	99/39726	08/1999	WIPO	Sykes				
	LR	99/42075	08/1999	WIPO	Aruffo et al.				
	MR	99/61051	12/1999	WIPO	Segal				
	NR	00/00156	01/2000	WIPO	Wade et al.				
	OR	00/75348 A1	12/2000	WIPO	Siegall et al.				
	PR	01/24823 A1	04/2001	WIPO	Chu et al.				
	QR	01/83755 A2	11/2001	WIPO	Mikayama et al.				
	RR	01/83755 A3	11/2001	WIPO	Mikayama et al.				

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Date Considered:

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OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

Examiner's Initials*			English Abstract		Translation Readily Available	
			Enclosed	No	Enclosed	No
	ZR	An et al.; Ligation of CD40 Potentiates Fas-Mediated Activation of the Cysteine Protease CPP32, Cleavage of Its Death Substrate PARP, and Apoptosis in Ramos-Burkitt Lymphoma B Cells; Cellular Immunology, vol. 181; 1997; pp. 139-152				
	AAR	Baccam et al.; Membrane-bound CD154, but not CD40-specific antibody, mediates NF- $\kappa$ B-independent IL-6 production in B cells; Eur. J. Immunol., vol. 29; 1999; pp. 3855-3866				
	BBR	Barr et al.; Functional activity of CD40 antibodies correlates to the position of binding relative to CD154; Immunology, vol. 102; 2001; pp. 39-43				
	CCR	Boon et al.; Preclinical assessment of anti-CD40 Mab 5D12 in cynomolgus monkeys; Toxicology, vol. 174; 2002; pp.53-65				
	DDR	Challa et al.; Epitope-dependent synergism and antagonism between CD40 antibodies and soluble CD40 ligand for the regulation of CD23 expression and IgE synthesis in human B cells; Allergy, vol. 54; 1999; pp. 576-583				
	EER	Clark et al.; Activation of human B cells mediated through two distinct cell surface differentiation antigens, Bp35 and Bp50; Proc. Natl. Acad. Sci. USA, vol. 83; June 1986; pp.4494-4498				
	FFR	Clark et al.; CDw40 and BLCa-specific monoclonal antibodies detect two distinct molecules which transmit progression signals to human B lymphocytes; Eur. J. Immunol., vol. 18; 1988; pp. 451-457				
	GGR	de Boer et al.; Generation of monoclonal antibodies to human lymphocyte cell surface antigens using insect cells expressing recombinant proteins; Journal of Immunological Methods, vol. 152; 1992; pp.15-23				
	HHR	Diehl et al.; CD40 activation <i>in vivo</i> overcomes peptide-induced peripheral cytotoxic T-lymphocyte tolerance and augments anti-tumor vaccine efficacy; Nature Medicine, vol. 5, no. 7; July 1999; pp. 774-779				
	IIR	Dullforce et al; Enhancement of T cell-independent immune responses <i>in vivo</i> by CD40 antibodies; Nature Medicine, vol. 4, no. 1; January 1998; pp. 88-91				
	JJR	Erickson et al.; Short-circuiting long-lived humoral immunity by the heightened engagement of CD40; The Journal of Clinical Investigation, vol. 109, no. 5; March 2002; pp. 613-620				

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Examiner's Initials*			English Abstract		Translation Readily Available	
			Enclosed	No	Enclosed	No
	KKR	Francisco et al.; Construction, Expression, and Characterization of BD1-G28-5 sFv, a Single-chain Anti-CD40 Immunotoxin Containing the Ribosome-inactivating Protein Bryodin 1; The Journal of Biological Chemistry, vol. 272, no. 39; September 1997; pp. 24165-24169				
	LLR	Francisco et al.; Agonistic Properties and in Vivo Antitumor Activity of the Anti-CD40 Antibody SGN-14; Cancer Research, vol. 60; June 2000; pp. 3225-3231				
	MMR	Funakoshi et al.; Inhibition of Human B-Cell Lymphoma Growth by CD40 Stimulation; Blood, vol. 83, no. 10; May 1994; pp. 2787-2794				
	NNR	Funakoshi et al.; Differential In Vitro and In Vivo Antitumor Effects Mediated by Anti-CD40 and Anti-CD20 Monoclonal Antibodies Against Human B-Cell Lymphomas; Journal of Immunotherapy, vol. 19, no. 2; 1996; pp. 93-101				
	OOR	Hasbold et al.; Properties of mouse CD40: cellular distribution of CD40 and B cell activation by monoclonal anti-mouse CD40 antibodies; Eur. J. Immunol., vol. 24; 1994; pp. 1835-1842				
	PPR	Hasbold et al.; Cell division number regulates IgG1 and IgE switching of B cells following stimulation by CD40 ligand and IL-4; Eur. J. Immunol., vol. 28; 1998; pp. 1040-1051.				
	QQR	Heath et al.; Monoclonal antibodies to murine CD40 define two distinct functional epitopes; Eur. J. Immunol., vol. 24; 1994; pp. 1828-1834				
	RRR	Hirano et al.; Inhibition of Human Breast Carcinoma Growth by a Soluble Recombinant Human CD40 Ligand; Blood, vol. 93, no. 9; May 1999; pp. 2999-3007				
	SSR	Karlsson et al.; Selection of human single chain antibodies against CD40; Immunology Letters, vol. 73, nos. 2, 3; September 2000; p. 161, abstract no. 358				
	TTR	Kedl et al.; CD40 stimulation accelerates deletion of tumor-specific CD8 <sup>+</sup> T cells in the absence of tumor-antigen vaccination; PNAS, vol. 98, no. 19; September 2001; pp. 10811-10816				
	UUR	Kwekkeboom et al.; CD40 plays an essential role in the activation of human B cells by murine EL4B5 cells; Immunology, vol. 79; 1993; pp. 439-444				
	VVR	Kwekkeboom et al.; Helper effector function of human T cells stimulated by anti-CD3 mAb can be enhanced by cd-stimulatory signals and is partially dependent on CD40-CD40 ligand interaction; Eur. J. Immunol., vol. 24; 1994; pp. 508-517				

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Initials\*

English

Abstract

Translation

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Available

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No

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No

WWR

Lagerkvist et al.; Single, Antigen-Specific B Cells Used to Generate Fab Fragments Using CD40-Mediated Amplification or Direct PCR Cloning; BioTechniques, vol. 18, no. 5; 1995; pp. 862, 864-869

XXR

Ledbetter et al.; Augmentation of Normal and Malignant B Cell Proliferation by Monoclonal Antibody to the B Cell-Specific Antigen BP50 (CDW40); The Journal of Immunology, vol. 138, no. 3; February 1987; pp. 788-794

YYR

Ledbetter et al.; Agonistic Activity of a CD40-Specific Single-Chain Fv Constructed from the Variable Regions of mAb G28-5; Critical Reviews in Immunology, vol. 17; 1997; pp. 427-435

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Malmborg Hager et al.; Affinity and Epitope Profiling of Mouse Anti-CD40 Monoclonal Antibodies; Scandinavian Journal of Immunology, vol. 57; 2003; pp. 517-524

AAAR

Maxwell et al.; Contrasting the Roles of Costimulation and the Natural Adjuvant Lipopolysaccharide During the Induction of T Cell Immunity; The Journal of Immunology, vol. 168; 2002; pp. 4372-4381

BBBR

Mazzei et al.; Recombinant Soluble Trimeric CD40 Ligand Is Biologically Active; The Journal of Biological Chemistry, vol. 270, no. 13; March 1995; pp. 7025-7028

CCCR

Murphy et al.; Antibodies to CD40 Prevent Epstein-Barr Virus-Mediated Human B-Cell Lymphomagenesis in Severe Combined Immune Deficient Mice Given Human Peripheral Blood Lymphocytes; Blood, vol. 86, no. 5; September 1995; pp. 1946-1953

DDDR

Paulie et al.; A p50 surface antigen restricted to human urinary bladder carcinomas and B lymphocytes; Cancer Immunology Immunotherapy, vol. 20; 1985; pp. 23-28

EEER

Pound et al.; Minimal cross-linking and epitope requirements for CD40-dependent suppression of apoptosis contrast with those for promotion of the cell cycle and homotypic adhesions in human B cells; International Immunology, vol. 11, no. 1; 1999; pp. 11-20

FFFR

Rolink et al.; The SCID but Not the RAG-2 Gene Product Is Required for  $\mu$ - $\kappa$  Heavy Chain Class Switching; Immunity, vol. 5; October 1996; pp. 319-330

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	GGGR	Romano et al.; Triggering of CD40 Antigen Inhibits Fludarabine-Induced Apoptosis in B Chronic Lymphocytic Leukemia Cells; Blood, vol. 92, no. 3; August 1998; pp. 990-995				
	HHHR	Schoenberger et al.; T-cell help for cytotoxic T lymphocytes is mediated by CD40-CD40L interactions; Nature, vol. 393; June 1998; pp. 480-483				
	IIIR	Schwabe et al.; Modulation of Soluble CD40 Ligand Bioactivity with Anti-CD40 Antibodies; Hybridoma, vol. 16, no. 3; 1997; pp. 217-226				
	JJJR	Sotomayor et al.; Conversion of tumor-specific CD4 <sup>+</sup> T-cell tolerance to T-cell priming through <i>in vivo</i> ligation of CD40; Nature Medicine, vol. 5, no. 7; July 1999; pp. 780-787				
	KKKR	Stamenkovic et al.; A B-lymphocyte activation molecule related to the nerve growth factor receptor and induced by cytokines in carcinomas; The EMBO Journal, vol. 8, no. 5; 1989; pp. 1403-1410				
	LLLR	Tomizuka et al.; Double trans-chromosomal mice: Maintenance of two individual human chromosome fragments containing Ig heavy and $\kappa$ loci and expression of fully human antibodies; PNAS, vol. 97, no. 2; January 2000; pp. 722-727				
	MMMR	van Mierlo et al.; CD40 stimulation leads to effective therapy of CD40 <sup>+</sup> tumors through induction of strong systemic cytotoxic T lymphocyte immunity; PNAS, vol. 99, no. 8; April 2002; pp. 5561-5566				
	NNNR	Weng et al.; Human Anti-CD40 Antagonistic Antibodies Inhibit the Proliferation of Human B Cell Non-Hodgkin's Lymphoma; Program of the 43 <sup>rd</sup> Annual Meeting of the American Society of Hematology; December 2001; page 466a, abstract no. 1947				
	OOOR	Zhou et al.; An Agonist Anti-Human CD40 Monoclonal Antibody that Induces Dendritic Cell Formation and Maturation and Inhibits Proliferation of a Myeloma Cell Line; Hybridoma, vol. 18, no.6; 1999; pp. 471-478				

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